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Patent

Attorney's Docket No. P-022-RC1

Customer No. 27038

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	)
JUDICE et al.	) Group Art Unit: 1653
Application No.: 10/092,088	) Examiner: David Lukton
Filed: March 6, 2002	)
For: GLYCOPEPTIDE DERIVATIVES AND PHARMACEUTICAL COMPOSITIONS CONTAINING THE SAME	) )

## INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure as set forth in 37 CFR §1.56, Applicants hereby submit the following information in conformance with CFR §§1.97 and 1.98. Enclosed herewith is form PTO-1449 which lists documents for consideration by the Examiner. Copies of the cited documents are also enclosed herewith.

The filing of this Information Disclosure Statement shall not be construed as a representation that a search has been made (37 C.F.R. §1.97(g)), or as an admission that the information cited is, or is considered to be, material to patentability (37 C.F.R. §1.97(h)).

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The documents listed as B1, B2, B13, B14, B15 and B17 on the enclosed form PTO-1449 were cited in the PCT International Search Report mailed on May 18, 2000, for the corresponding PCT Application No. PCT/US99/30543. A copy of the PCT International Search Report is enclosed herewith for the convenience of the Examiner.

Additionally, the documents listed as A4, B1, B2, B14, B15, B19, and B22 on the enclosed form PTO-1449 were cited in the Search Report completed by the Austrian Patent Office on January 7, 2002, on behalf of the Intellectual Property Office of Singapore, for the corresponding Singaporean application. A copy of the Austrian Patent Office Search Report is also enclosed for the convenience of the Examiner.

Pursuant to 37 C.F.R. §1.98(a)(3)(i), a concise explanation of the relevance of the following non-English language document is provided:

(1) FUKUZAWA et al., "Modification of sugar part of glycopeptide antibiotic, vancomycin", Tennen Yuki Kagobutsu Toronkai Koen Yoshishua, 40th, pp 151-156 (1998) discloses various derivatives of vancomycin in which the C6 position of the glucose moiety in vancomycin has been modified to incorporate a functional group. An English-language abstract and an English-language translation of this document are also enclosed herewith.

Consideration of the documents listed on the enclosed PTO-1449 is respectfully requested. Additionally, the Examiner is respectfully requested to return an initialed copy of the enclosed form PTO-1449 to Applicants.

Additionally, Applicants hereby bring to the Examiner's attention the following commonly-assigned, copending applications and issued patents:

- (1) U.S. Patent No. 6,392,012, issued May 21, 2002;
- (2) U.S. Patent No. 6,444,786, issued September 3, 2002;
- (3) U.S. Patent No. 6,455,669, issued September 24, 2002;
- (4) U.S. Serial No. 09/776,466, filed February 2, 2001;
- (5) U.S. Serial No. 09/847,041, filed May 1, 2001;
- (6) U.S. Serial No. 09/847,042, filed May 1, 2001;
- (7) U.S. Serial No. 10/436,341, filed May 12, 2003;
- (8) U.S. Serial No. 09/847,052, filed May 1, 2001;
- (9) U.S. Serial No. 10/601,847, filed June 23, 2003;

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- (10) U.S. Serial No. 09/847,048, filed May 1, 2001; and
- (11) U.S. Serial No. 09/847,061, filed May 1, 2001.

This Information Disclosure Statement is being filed before the mailing date of a first official action on the merits for this application and therefore, no fee or certification is required under 37 CFR §1.97(b). In the event that an Office Action is mailed prior to receipt of this paper, the Commissioner is hereby authorized to charge the requisite fees under 37 CFR §1.97(c) for submission of this paper to Deposit Account No. 50-0344.

Should there be any questions concerning the cited documents, the Examiner is encouraged to telephone the undersigned attorney for Applicants at (650) 808-6406 (direct).

Respectfully submitted,

THERAVANCE, INC.

ا Date:

V

THERAVANCE, INC. 901 Gateway Boulevard South San Francisco, CA 94080

Tel: (650) 808-6000 Fax: (650) 808-6078

Attorney Docket No. P-022-RC1 Application Serial No.: 10/092,088

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PTO/SB/08a (08-03)

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE er the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE

 C mplete if Known

 Application Number
 10/092,088

 Filing Date
 March 6, 2002

 First Named Inventor
 J. Kevin JUDICE

 Art Unit
 1653

 Examiner Name
 David LUKTON

(Use as many sheets as necessary)

STATEMENT BY APPLICANT

form 1449A/PTO

Sheet 1 of 4 Attorney Docket Number P-022-RC1

			U.S. PA	TENT D	OCUME	NTS			
Examiner Initials *	Cite No.1	Document Number  Number - Kind Code <sup>2</sup> (if known)	Publication Date		Name of Patentee or Applicant of Cited Document		of	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
	A1	US-4,497,802	02-05-1985		Debono			rigules Appeal	
	A2	US- 4,639,433	01-27-1987		Hunt et al.		$\dashv$		
	A3	US- 4,643,987	02-17-1987		Nagarajan et al.		_		
	A4	US- 4,661,470	04-28			alabarba et al.	_		
	A5	US- 4,698,327		-1987	Nagarajan et al.		$\neg$		
	A6	US- 4,914,187		-1990		alabarba et al.			
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	A8	US- 5,591,714	01-07		Na	agarajan et al.			
·	A9	US- 5,750,509		-1998		alabarba et al.			
	A10	US- 5,840,684		-1998		Cooper et al.			
	A11	US- 5,843,889	12-01	-1998		Cooper et al.			
	A12	US- 5,916,873		-1999	(	Cooper et al.			
	A13	US- 5,919,756	07-06-1999		Cooper et al.				
	A14	US- 5,952,310	09-14	09-14-1999 09-14-1999		Thompson et al. Berglund et al.			
	A15	US- 5,952,466	09-14						
	A16	US- 5,977,062	11-02	-1999	(	Cooper et al.			
	A17	US- 5,977,063	11-02	-1999	Th	nompson et al.			
	A18	US- 5,998,581	12-07-1999		Berglund et al.				
	·		FORE	IGN PA	TENT D	OCUMENTS			
		Foreign Patent Docum	nent			Name of Patente	e or	Pages, Columns, Lines,	
Examiner Initials*	Cite No. <sup>1</sup>	Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)		Publication Date MM-DD-YYYY		Applicant of Cited Document		Where Relevant Passages or Relevant Figures Appear	T <sup>®</sup>
	B1	WO 88/06600 A1		09-07-1988		Gruppo Lepe S.P.A.	ı		
	B2	WO 90/11300 A1		10-04-1	1990	Gruppo Lepe S.P.A.	etit		
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	B5	WO 97/38702 A1	O 97/38702 A1		10-23-1997				
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	B7	WO 98/21952 A1	O 98/21952 A1		1998	Eli Lilly and Company			
	B8	WO 98/52589 A1		11-26-	1998	Eli Lilly and Company			
	B9	WO 98/52592 A1		11-26-	1998	Eli Lilly and Company			
	B10	WO 99/42476 A1		08-26-	1999	Advanced Medicine, Inc	c.		
	B11	WO 99/56760 A1		11-11-	1999	Eli Lilly and Company			
	B12	WO 00/04044 A1		01-27-2	2000	Princeton University			
	B13	EP 0 182 157 A2		05-28-	1986	Gruppo Lepe S.P.A.	etit		
Examiner Signature					Date Consid	lered			

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Substitute for form 1449B/PTO C mplete if Known Application Number 10/092,088 **INFORMATION DISCLOSURE** Filing Date March 6, 2002 STATEMENT BY APPLICANT First Named Inventor J. Kevin JUDICE Art Unit 1653 (Use as many sheets as necessary) Examiner Name David LUKTON Sheet 2 of 4 Attorney Docket Number P-022-RC1

		FOREIGN	PATENT DO	CUMENTS	3		
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document  Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Applican	e of Patentee or it of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	B14	EP 0 351 597 A2	01-24-1990	Grupp S.P.A	o Lepetit		
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	B19	EP 0 667 353 A1	08-16-1995		y and		
	B20	EP 0 801 075 A1	10-15-1997	Eli Lili Comp	y and anv		
	B21	EP 0 802 199 A2	10-22-1997	1 - 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	y and		
	B22	EP 0 816 378 A1	01-07-1998		y and		
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	C5	COOPER et al., "Chapter 14. Semi Chemistry, Volume 31, pp 131-140	isynthetic Glyco	peptide Antib	piotics", Annual R	eports in Medicinal	
	C6	FUKUZAWA et al., "Modification of Kagobutsu Toronkai Koen Yoshish translation)	sugar part of g ua, 40th, pp 15	ycopeptide a 1-156 (1998)	intibiotic, vancom (in Japanese wit	nycin", Tennen Yuki th English language	
_	C7	GE et al., "Vancomycin Derivatives D-Ala", Science, Vol. 284, pp 507-5		ptidoglycan E	Biosynthesis With	out Binding D-Ala-	
	C8	KERNS et al., "Synthesis and Antib the Glycopeptide Antibiotic Vancon Boston, MA, August 23-27, 1998					
	C9	MACKAY et al., "Glycopeptide Anti Biological Signaling", J. Am. Chem.				ization: A Model for	
Examiner Signature			Da Co	e nsidered			

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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P-022-RC1

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Attorney Docket Number

Substitute of April 198/PTO Complete if Known Application Number 10/092,088 INFORMATION DISCLOSURE Filing Date March 6, 2002 STATEMENT BY APPLICANT First Named Inventor J. Kevin JUDICE Art Unit 1653 (Use as many sheets as necessary) Examiner Name **David LUKTON** 

4 of

Sheet

	<del></del>	NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No.1					
	C10	MALABARBA et al., "Amides of De-Acetylglucosaminyl-Deoxy Teicoplanin Active Against Highly Glycopeptide-Resistant Enterococci", Vol. 47, No. 12, pp 1493-1506 (1994)				
	C11	MALABARBA et al., "Glycopeptide resistance in multiple antibiotic-resistant Gram-positive bacteria: a current challenge for novel semi-synthetic glycopeptide derivatives", Eur. J. Med. Chem., Vol. 32, pp 459-478 (1997)				
	C12	MALABARBA et al., "New Semisynthetic Glycopeptides MDL 63,246 and MDL 63,042, and Other Amide Derivatives of Antibiotic A-40,926 against Highly Glycopeptide-resistant VanA Enterococci", The Journal of Antibiotics, Vol. 48, No. 8, pp 869-883 (1995)				
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	C17	MALABARBA et al., "Synthesis and Biological Properties of $N^{63}$ —Carboxamides of Teicoplanin Antibiotics. Structure-Activity Relationships", J. Med. Chem., Vol. 32, pp 2450-2460 (1989)				
	C18	NAGARAJAN, "Structure-Activity Relationships of Vancoymycin-Type Glycopeptide Antibiotics", The Journal of Antibiotics, Vol. 46, No. 8, pp 1181-1195 (1993)				
	C19	NAGARAJAN et al., "Synthesis and Antibacterial Activity of <i>N</i> -Acyl Vancomycins", The Journal of Antibiotics, Vol. XLI, No. 10, pp 1430-1438 (1988)				
	C20	NAGARAJAN et al., "Synthesis and Antibacterial Evaluation of N-Alkyl Vancomycins", The Journal of Antibiotics, Vol. XLII, No. 1, pp 63-72 (1989)				
	C21	NICOLAOU et al., "Chemistry, Biology, and Medicine of the Glycopeptides Antibiotics", Angew. Chem. Int. Ed., Vol. 38, pp 2096-2152 (1999)				
	C22	OLSUFYEVA et al., "Chemical Modification of Antibiotic Eremomycin at the Asparagine Side Chain", The Journal of Antibiotics, Vol. 52, No. 3, pp 319-324 (1999)				
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	C24	PAVLOV et al., "Chemical Modification of Glycopeptide Antibiotics [VC1], Russian Journal of Bioorganic Chemistry, Vol. 24, No. 9, pp 570-587 (1998)				
	C25	PAVLOV et al., "Mono and Double Modified Teicoplanin Aglycon Derivatives on the Amino Acid No. 7; Structure-activity Relationship", The Journal of Antibiotics, Vol. 51, No. 1, pp 73-78 (1997)				
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<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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SEP 1 5 2003

		NON PATENT LITERAT	URE DOCUMENTS			
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.				
	C26	RODRIGUEZ et al., "Novel Glycopeptide Antil Vancomycin-Resistant Enterococci", Vol. 51, I				
	C27	SHARMAN et al., "The Roles of Dimerization Antibiotics against Vancomycin-Resistant Bac (1997)	and Membrane Anchoring in Activity of Glycopeptid teria", J. Am. Chem. Soc., Vol. 119, pp 12041-1204	<del>)</del>		
	C28	SNYDER et al., "Enzymatic Deacylation of Te and Antibacterial Activity of New Glycopeptide 951 (1998)	coplanin Followed by Reductive Alkylation:Synthes s", The Journal of Antibiotics, Vol. 51, No. 10, pp 9-	s 15-		
	C29	STAROSKE et al., "Synthesis of Covalent Head-to-Tail Dimers of Vancomycin", Tetrahedron Letters 39, pp 4917-4920 (1998)				
C30 SUNDRAM et al., "Novel Vancomycin Dimers with Activity against Vancomycin-Resistant Enterococci", J. Am. Chem. Soc., Vol. 118, pp 13107-13108 (1996)						
Examiner Signature			Date Considered	<u> </u>		

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.